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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 09/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/616,942	KATO ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 August 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *19-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *19-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/529,100.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

The amendment filed 11 July 2003 has been entered in full. Claims 1-6 were cancelled. New claims 7-18 were added. The amendment filed 30 August 2004 has been entered in full. Claims 7-18 were cancelled. New claims 19-30 were added.

Applicant's election with traverse of SEQ ID NOs 3, 9 and 17 in the reply filed on 21 June 2004 is acknowledged. The traversal is on the grounds that the requirement is not understood because MPEP 803.04 makes clear that normally ten distinct sequences encoding separate proteins are to be considered a single invention. Applicant has requested the Examiner to explain why Applicants are not afforded the opportunity to select nine additional species.

This is not found persuasive because each case is examined on its own merits. However, in the instant case, the sequences are sufficiently diverse to warrant restriction based upon the search burden that would be necessitated by searching ten sequences. For example, claim 23 recites, "an isolated polynucleotide which encodes a polypeptide comprising the amino acid sequence set forth in SEQ ID NO:3 or the complement of said isolated polynucleotide. SEQ ID NO:3 is drawn to the polypeptide, SEQ ID NO:9 is drawn to the cDNA and SEQ ID NO:17 is drawn to the polynucleotide comprising untranslated sequences. The search of SEQ ID NO:3 would not only encompass searching the polypeptide database, but the polynucleotide database, which encodes the polypeptide. Applicants are actually getting many more than 10 sequences

considering the comprising language, complements of polynucleotide sequences and variants encompassed by the claims (e.g., degenerate sequences, derivatives, etc.).

The requirement is still deemed proper and is therefore made FINAL. Applicant timely traversed the restriction (election) requirement in the reply filed on 21 June 2004. Claims 19-30 are under examination.

Information Disclosure Statement

The information disclosure statement (IDS) submitted 11 July 2003 was received and complies with the provisions of 37 CFR §§1.97 and 1.98. It has been placed in the application file and the information referred to therein has been considered as to the merits. However, since the Blast results cited therein are not true publications with a publication date, they are not fully in compliance with 37 CFR 1.97 and thus they will not be printed on the face of the patent issuing from this application.

Specification

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

Sequence Rules

The specification is not in compliance with 37 CFR 1.821-1.825 of the Sequence Rules and Regulations. When the description of a patent application discusses a sequence listing that is set forth in the "Sequence Listing" in accordance with paragraph

(c) of the Sequence Rules and Regulations, reference must be made to the sequence by use of the assigned identifier (SEQ ID NO:), in the text and claims of the patent application.

37 CFR 1.821(a) presents a definition for nucleotide and/or amino acid sequences. This definition sets forth limits in terms of numbers of amino acids and/or numbers of nucleotides, at or above which compliance with the sequence rules is required. Nucleotide and/or amino acid sequences as used in 37 CFR 1.821 through 1.825 are interpreted to mean an unbranched sequence of four or more amino acids or an unbranched sequence of ten or more nucleotides. Please see MPEP section 2422.01.

The specification refers to sequences in Tables 2, 3 and 4 (pages 47, 48 and 53) but does not identify the sequences by their sequence identifiers. Sequences appearing in drawings may be referenced in the drawings themselves or in the corresponding Brief Description thereof. Appropriate correction is required. **Applicant must submit a response to this Office Action and compliance with the sequence rules within the statutory period set for response to this Office Action.**

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim Rejections - 35 USC § 112, First Paragraph, Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 19-30 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well established utility.

The instant claims are drawn to the isolated polypeptide (SEQ ID NO:3) and isolated nucleotides (SEQ ID NO:9 and SEQ ID NO:17) the vector, host cell and the method of making and isolating the polypeptide. The specification states that the invention relates to human proteins having transmembrane domains and cDNAs coding for these proteins as well as eukaryotic cells expressing said cDNAs.

The specification states that the primary selection of one of the cDNAs coding for human proteins having transmembrane domains is carried out by sequencing of a partial base sequence of a cDNA clone selected at random from cDNA libraries, sequencing of the amino acid sequence encoded by the base sequence and the presence or absence of a hydrophobic site in the resulting N-terminal amino acid sequence (page 8, lines 13-26). The cDNA of clone HP10089 was obtained from cDNA libraries of human liver (page 9, Table 1 and page 49, lines 13-27). The specification reports that the search of the protein database using the amino acid sequence of the present protein (SEQ ID NO:3) has not revealed the presence of any known protein having an analogy. The search of the GenBank using the base sequences of presence

present CDNA has revealed the presence of sequences that possessed a homology of 90% or more and contained an initiation codon, but since they are partial sequences, it cannot be judged whether or not any of these sequences codes for the same protein as the protein of the present invention (page 49, line 25-page 50, line 6).

The specification does not disclose that SEQ ID NO:3 has significant homology to other, prior art proteins. The instant specification does not disclose any additional information regarding SEQ ID NO:3 such as subcellular location, timing of regulation during cellular differentiation, which hormones or transcription factors regulate SEQ ID NO:3, and what physiological significance SEQ ID NO:3 plays. The utility of a claimed DNA does not necessarily depend on the function of the encoded gene product, if the claimed DNA (SEQ ID NO:9 and SEQ ID NO:17) had a specific and substantial utility such as it hybridizes near a disease-associated gene or it has a gene regulating activity. The specification, however, fails to disclose that the polynucleotides of the instant application can be linked to a specific disease or gene regulating activity.

The specification also generally asserts that all of the disclosed polynucleotides and polypeptides will be useful for a number of purposes; however, none of these asserted uses meet the three-pronged requirement of 35 U.S.C. § 101 regarding utility, namely, that the asserted utility be specific and substantial. Some of the asserted utilities will each be addressed.

1) the claimed polynucleotide can be used to encode the claimed polypeptide, which can be used to isolate other polypeptides to which it binds: This asserted utility is not specific or substantial. Since the same can be done with any encoded polypeptide,

the asserted utility is not specific to the claimed polynucleotide. Furthermore, since the specification does not disclose how the claimed polypeptide or its binding partners can be used, significant further research would be required of the skilled artisan to determine how to use the claimed polypeptide or its binding partner. Since the asserted utility is not presented in a ready to use, real-world application, the asserted utility is not substantial.

2) the claimed polynucleotide can be used to encode the claimed polypeptide, which can be used as markers for tissues in which the corresponding polypeptide is preferentially expressed: This asserted utility is not specific or substantial. With the exception of a few housekeeping genes, all polypeptides have a tissue specific pattern of expression, and thus virtually any polypeptide can be used in tissue typing. Thus, the asserted utility is not specific to the claimed polypeptide.

3) the claimed polynucleotide can be used to encode the claimed polypeptide, which can be used for therapeutics: This asserted utility is not specific or substantial. Since a defect in any polynucleotide is likely to cause a disease of some sort, every polypeptide is a target for drug development. Thus, the asserted utility is not specific to the claimed polypeptide. Furthermore, the specification does not disclose a nexus between any specific disease states and a change in amount or form of the claimed polypeptide. Significant further research would have to be conducted to identify such a nexus. Therefore, the asserted utility is not substantial.

4) the claimed polynucleotide can be used as probes: Since the same can be done with any polynucleotide, the asserted utility is not specific to the claimed polynucleotide.

5) the claimed polynucleotide can be used as an antigen to raise anti-DNA antibodies: Since the same can be done with any polynucleotide, the asserted utility is not specific to the claimed polynucleotide.

1) the claimed polypeptide can be used to isolate other polypeptides to which it binds: This asserted utility is not specific or substantial. Since the same can be done with any polypeptide, the asserted utility is not specific to the claimed polypeptide. Furthermore, since the specification does not disclose how the claimed polypeptide or its binding partners can be used, significant further research would be required of the skilled artisan to determine how to use the claimed polypeptide or its binding partner. Since the asserted utility is not presented in a ready to use, real-world application, the asserted utility is not substantial.

2) the claimed polypeptide can be used to make antibodies: This asserted utility is not specific. Since the same can be done with any polypeptide, the asserted utility is not specific to the claimed polypeptides.

3) the claimed polypeptide can be used in tissue typing: This asserted utility is not specific or substantial. With the exception of a few housekeeping genes, all polypeptides have a tissue specific pattern of expression, and thus virtually any

polypeptide can be used in tissue typing. Thus, the asserted utility is not specific to the claimed polypeptide.

4) the claimed polypeptide can be used in therapy: This asserted utility is not specific or substantial. Since a defect in any polypeptide is likely to cause a disease of some sort, every polypeptide is a target for drug development. Thus, the asserted utility is not specific to the claimed polypeptide. Furthermore, the specification does not disclose a nexus between any specific disease states and a change in amount or form of the claimed polypeptide. Significant further research would have to be conducted to identify such a nexus. Therefore, the asserted utility is not substantial.

5) the claimed polypeptide can be used to identify agonists or antagonists: Since the same can be done with any polypeptide, the asserted utility is not specific to the claimed polypeptide. Furthermore, since no activity has been assigned, the assays cannot be conducted until the specific biological activities of the claimed polypeptide are determined empirically. Therefore, the asserted utility is also not substantial.

The proposed uses of the claimed polynucleotides and polypeptide are simply starting points for further research and investigation into potential practical uses of the polypeptides. See Brenner v. Manson, 148 U.S.P.Q. 689 (Sus. Ct, 1966), wherein the court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is

> not a reward for the search, but compensation for its successful conclusion."

Claims 19-30 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description

Claim 26 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claim is drawn to an isolated polynucleotide that hybridizes under wash conditions of 0.3xSSC at 65°C to the polynucleotide of claim 24 or a complement of said isolated polynucleotide. Claim 24 is drawn to an isolated polynucleotide comprising the base sequence set forth in SEQ ID NO:9, or a complement of said isolated polynucleotide.

Claim 26 recites clear hybridization conditions, but the instant specification fails to teach an activity for the polypeptide encoded by SEQ ID NO:9 (please see the 101/112 rejection). Thus claim 26 encompasses variants with no activity. In absence of sufficient recitation of distinguishing identifying characteristics, the specification does

not provide adequate written description of the claimed genus. There is no description of variants of SEQ ID NO:9 that exist, while still maintaining a function.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111, clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116).

With the exception of SEQ ID NO:9, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, and therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it. The compound itself is required. See Fiers v. Revel, 25 USPQ2d 1601 at 1606 (CAFC 1993) and Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016.

One cannot describe what one has not conceived. See Fiddes v. Baird, 30 USPQ2d 1481 at 1483. In Fiddes, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Therefore, only isolated polynucleotides comprising the nucleic acid sequence set forth in SEQ ID NO:9, but not the full breadth of the claim meets the written

description provision of 35 U.S.C. §112, first paragraph. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 28-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 28 recites, "a host cell". It is indefinite because it is unclear whether the claim is directed to an *isolated* host cell or encompasses whole transgenic organisms such as humans.

Claim 29 is drawn to a method of producing a polypeptide comprising culturing the host cell of claim 28 under conditions such that the polynucleotide is expressed. Claim 30 is drawn to the method of claim 29 further comprising isolating the polypeptide from the host cell or the medium in which the host cell is cultured.

Claims 29 and 30 are indefinite because they depend from claims, which recite the isolated polynucleotide or the complement of said isolated polynucleotide. Scientifically, a polypeptide cannot be made from a non-coding strand.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda G. Brumback can be reached on (571) 272-0961. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RMD
9/3/04

Elizabeth C. Kemmerer

ELIZABETH KEMMERER
PRIMARY EXAMINER